OCT 22 2001

K011502

XIV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Page)

A. Submitter: Clint Folsom, Crystal Medical Technology, Inc., 181 Cahaba Valley Pkwy, Pelham, AL 35124. Registration No. 51805.

I. Classification Name and Number: Endosseous Implant (76DZE),

II. Common/Usual Name: Dental Implant, Endosseous, Post (or screw)-type, titanium alloy.

III. Proprietary Name: CRYSTAL and CRYSTAL-Care Implants System

IV. Classification: This device is in Class III but is scheduled for down-classification by the Dental Devices Panel (Title 21 CFR 872.3640).

V. Performance standards: None applicable. Materials meet ASTM voluntary standards

VI. Description: The CRYSTAL-Care Implants System implants are post-type endosseous dental implants with design and manufacturing concepts, materials, surgical procedures, and intended uses quite similar to the preamendment device and to others rated substantially equivalent to the preamendment device. This CRYSTAL-Care system is most similar to the Crystal and Crystal Seal Implants System which received concurrence of substantial equivalence from the Food and Drug Administration in premarket notification submissions K-954432 and K980447. Like many commercial implants, the CRYSTAL-Care devices are manufactured of titanium alloy (ASTM F 136-84 titanium - 6 aluminum - 4 vanadium).

CRYSTAL-Care Implants are available in grit blasted form. These devices are equivalent to various uncoated endosseous implants on the market, for example The ITI Dental Implant System, by The Strauman Company, which were cleared under K984104 and K002374, the Bicortical Screw by Oraltronics in K983120, and Steri-Oss Implants by Steri-Oss Inc, in K983120.

VII. Labels and Instructions for Use are provided, as are labels for competitive products.

VIII. Intended Use: These devices are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices and to restore the patient's chewing function.

IX. Substantial Equivalence: This device is equivalent to devices manufactured and sold before 1976,having a U. S. classification number of 76 DZE, and those described under 21 CFR 872.3640. It is also equivalent to several devices currently on the market that have been determined by the FDA to be substantially equivalent to the above preamendment devices, particularly to Crystal and Crystal Plus System cleared by K954432 and K980447. Some examples of other equivalent products are:
The ITI Dental Implant System, by The Strauman Company, which were cleared under K984104 and K002374, the Bicortical Screw by Oraltronics in K983120, and Steri-Oss Implants by Steri-Oss Inc, in K983120.

X. Clinical Discussion and Brief Literature Review: Endosseous implants, and especially those of titanium or titanium alloy, in the "post" or "screw" configuration, have been proved safe and effective through the years. The possible adverse effects summarized in this 510(k) cover those listed by the United States classification panel [Federal Register, vol. 45, No. 251, pp 86025-6, Dec. 30, 1980], as well as to those revealed in a recent literature search. Matukas, "Medical Risks Associated with Dental Implants," states, "Little or no hard data could be found on the medical risks associated with [dental] implants." Because of the wide-spread usage of dental implants, Smith and Zarb made a careful review of the literature and proposed criteria for implant success.

A thorough computerized Medline literature search produced 585 entries. An update of this search produced 68 new review articles. The Journal of Dental Education published a special issue "Proceedings of the Consensus Development Conference on Dental Implants [National Institutes of Health, Bethesda, MD, June 13-15, 1988], Vol. 52, No. 12, pp. 677-831, Dec. 1988. This added to the literature search above, with some especially pertinent reprints from the scientific literature, provide a comprehensive summary of available scientific data.

Zarb completed his report of the detailed Toronto 10-year study by concluding that "the tried and tested Branemark implant technique has revolutionized the treatment options open to the prosthodontist. For the edentulous patient...the prospect for a lifetime of restored oral comfort, function, and appearance have now become predictable and reliable." These results are ample evidence of the safety and effectiveness of these endosseous implants.

END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2001

Mr. Clint Folsom
President
Crystal-Seal Denatl Implants
181 Valley Parkway
Pelham, Alabama 35124

Re: K011502
Trade/Device Name: Crystal-Care™
Regulation Number: 872.3640
Regulation Name: Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: August 8, 2001
Received: August 10, 2001

Dear Mr. Folsom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011502

IX. Indications for Use: [Separate Page]

510(k) Number: ~~NA~~

Device Name: Crystal-Care ™

This device is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

The device should be loaded with prosthetic components after an appropriate healing time has elapsed since placement. Six months healing time is recommended for both upper and lower arches.

If the phrase immediate load is noted in any part of this submission it should be disregarded.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011502